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Appellant,

v.

District Court for the District of Nebraska.

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Appellees.

Filed: July 12, 1996

Before EAM and MORRIS SHEPPARD ARNOLD, Circuit Judges, and JONES,* District Judge.

BEAM, Circuit Judge.

Kipp (Kipp) appeals the district court's g
judgment to the gover
recover damages for the death of his mother (Cheryl Kipp)

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Judge for the District of Nebraska.

due to a blood transfusion contaminated with the human immunodeficiency virus (HIV). Because Kipp failed to prove causation, a required element of his negligence claims, we affirm.

I. BACKGROUND

Kipp brought this negligence action under the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b) & 2671, both in his individual capacity and in his capacity as the representative of Cheryl Kipp's estate. The HIV-contaminated blood was donated on January 16, 1985, at Camp Memorial Blood Center (Blood Center) by Darryl Bonner when he was in basic training for the United States Army in Kentucky. Cheryl Kipp received the transfusion in February of 1985 while undergoing a hysterectomy at Ehrling Bergquist Hospital at Offutt Air Force Base in Nebraska. In May 1989, Cheryl Kipp died from complications associated with acquired immunodeficiency syndrome (AIDS).

Reported cases involving the transmission of AIDS through blood transfusions first appeared in 1982. In response to that newly-discovered threat, in March 1983, the Food and Drug Administration (FDA) issued a memorandum advising all establishments collecting blood for transfusion to provide: (1) educational programs informing persons in certain "high risk" groups that they should refrain from donating blood until a definitive AIDS test was developed; (2) re-education of personnel responsible for donor screening to identify signs and symptoms of AIDS in potential donors; and (3) a standard operating procedure whereby blood collected from a donor suspected of having AIDS was labeled or quarantined and destroyed.

In December 1984, the FDA issued another memorandum to all registered blood banks in the United States. In this document, the FDA stated that blood banks should: (1) provide educational materials to potential donors in order to inform them of which

groups were at high risk of contracting or carrying HIV; (2) ask donors specific questions about their medical histories in order to determine whether a donor may have contracted HIV; (3) provide donors with a confidential means of preventing their blood or plasma from being used in a transfusion or in making plasma derivatives; and (4) institute special procedures for handling blood products known to be infected with HIV. These December 1984 recommendations were adopted by the Army on February 13, 1985.

In January 1985, when Bonner donated his blood, there was no scientifically reliable test to determine whether blood was infected with The Blood Center staff conducted an orientation, pursuant to their standard procedure, for all potential blood donors, including Bonner. received a pamphlet that identified groups at high risk of contracting AIDS, and requested people who thought they fell into one of these groups to refrain from donating blood. The pamphlet described specific signs and Additionally, a Blood Center employee read the AIDS symptoms of AIDS. informational material aloud to potential donors. Moreover, each donor, including Bonner, received a card which requested information regarding that person's health. Bonner completed, and signed, the donor card on which he indicated he was in good health. Rachel Harris Demaree, a senior sergeant at the Blood Center, conducted a confidential interview and reviewed Bonner's answers on the donor card with him. Demaree and a phlebotomist at the Blood Center then conducted a physical examination of Bonner, during which his arms were examined and his vital signs obtained. Demaree also checked Bonner for Kaposi's sarcoma, a rare form of cancer sometimes associated with AIDS, but found no indications of the disease. Later, however, Bonner tested positive for HIV. In April 1989, he died from AIDS-related complications.

At trial, Kipp claimed that the Blood Center was negligent in its screening of the blood because it failed to follow FDA

recommendations on proper screening procedures. After conducting a bench trial, the district court held that Kipp failed to prove his negligence claims and granted judgment to the defendants. Applying a professional standard of care analysis, the district court stated that Kipp failed to provide any expert testimony on the standard of care for blood banks in Kentucky and relied instead on a negligence claim based on FDA recommendations, which the court concluded did not establish the applicable standard of care. The district court also affirmed the magistrate judge's order prohibiting all of Kipp's lay witnesses from testifying due to a violation of the court's progression order.

On appeal, Kipp first contends that the industry standards of military blood gathering are controlled by the Military Blood Program Office (MBPO) operating under the FDA recommendations. Because these recommendations were not followed in the present case, Kipp asserts the defendants' actions constitute negligence per se. Kipp also argues that the order to exclude all of his lay witnesses violates the law of this circuit. Finally, he alleges that under Kentucky law an ordinary standard of negligence, rather than a professional standard, applies to blood banks.

The defendants assert that the applicable standard of care under Kentucky law is the professional standard. They also contend, however, that their actions satisfied any negligence standard. Moreover, according to the defendants, Kipp failed to establish any causal link between the alleged deficiencies in the screening process and Cheryl Kipp contracting AIDS. The defendants also argue that striking all lay witness did not "constitute a dismissal," as Kipp contends, because the magistrate judge has broad discretion in fashioning remedies for a violation of a discovery order, including prohibiting the admission of evidence. Lastly, the defendants raise the discretionary function exception to the Federal Tort Claims Act as a defense.

II. DISCUSSION

This tragic case requires us to determine whether Kipp proved that the defendants were negligent in screening or taking the HIV contaminated blood, thereby causing his mother to contract the fatal virus. Kipp asserts that the defendants' failure to comply with the FDA recommendations constitutes negligence per se. Moreover, according to Kipp, failure to comply with the FDA recommendations also violated an applicable Kentucky statute, thereby constituting negligence per se. Assuming, without deciding, the validity of Kipp's position, negligence per se would only satisfy the duty and breach of duty elements of his negligence claims. See generally Restatement (Second) of Torts § 288B cmt. b (1965). Therefore, Kipp must still prove that the alleged breach—i.e., inadequate screening of the donor for HIV—caused his mother to contract AIDS. See, e.g., Peak v. Barlow Homes, Inc., 765 S.W.2d 577, 578 (Ky. Ct. App. 1988).

Under Kentucky law, a plaintiff bears the burden of proving that a defendant's negligent act or omission was "a substantial factor in bringing about the injury." See, e.g., Brown Hotel v. Levitt, 209 S.W.2d 70 (Ky. 1948). In further refining this "substantial factor" analysis, the Supreme Court of Kentucky reasoned: "`In order to be a legal cause of another's harm, it is not enough that the harm would not have occurred had the actor not been negligent. . . . [T]his is necessary, but it is not of itself sufficient.'" Deutsch v. Shein, 597 S.W.2d 141, 144 (Ky. 1980) (adopting and quoting the Restatement (Second) of Torts § 431, cmt. a (1965)); see also W. Page Keeton, et al., Prosser and Keeton on the Law of Torts § 41, at 265 (5th ed. 1984) ("An act or omission

 $^{^2}$ The statute that Kipp argues applies in this case mandates that "[a]ll blood establishments within the Commonwealth shall be licensed by the United States Food and Drug Administration and remain in compliance with all applicable federal regulations." Ky. Rev. Stat. § 214.452(1).

is not regarded as a cause of an event if the particular event would have occurred without it."). Therefore, because Kipp based his negligence claims on an inadequate screening theory, he needed to provide some evidence that had the defendants complied with the FDA recommendations, Bonner's infected blood would not have been taken and given to Cheryl Kipp. See, e.g., Tennyson v. Brower, 823 F. Supp. 421, 424 (E.D. Ky. 1993) (stating that it is clear under Kentucky law that the plaintiff in a negligence case bears the burden of proving that the negligent conduct had such an effect in producing the harm that a reasonable juror would regard it as a cause), aff'd, 27 F.3d 567 (6th Cir. 1994) (Table) (unpublished disposition).

We recognize the difficulty of demonstrating that Cheryl Kipp would not have contracted AIDS had the defendants followed FDA recommendations when, as in the present case, the donor died before trial. evidence existed, however, Kipp could have introduced it without the donor--e.g., if a friend saw Bonner about the time he donated his blood and the friend observed physical manifestations of symptoms associated with AIDS. Other courts have also recognized the difficulty of establishing causation in this type of case and the importance of information about the donor in order to enable the plaintiff to prove proximate cause. See, e.g., Long v. American Red Cross, 145 F.R.D. 658, 663 (S.D. Ohio 1993) ("Whether the employment of different tests or screening procedures would have produced a different result is a vital link in the plaintiffs' attempt to prove proximate cause."). As one plaintiff in a different case argued in his motion to compel: "Without an opportunity to ask the donor how he would have responded had the Red Cross followed proper screening procedures it will be virtually impossible for the plaintiff to prove that the Red Cross' negligence was the proximate cause of [the injury]." Ellison v. American Nat'l Red Cross, 151 F.R.D. 8, 11 (D.N.H. 1993). Nevertheless, even though it may have been more difficult without

the donor present, Kipp was not relieved of his burden of proving the requisite causation element.

Kipp asserts that the defendants failed to follow the procedures set out in the FDA recommendations in several respects. First, Kipp claims that the defendants failed to implement the FDA recommendations of December 14, 1984, in a timely manner. Next, Kipp argues that the FDA handout given to potential blood donors stated that Haitian entrants to the United States since 1979 should refrain from giving blood; while the FDA recommendation contained the same restriction beginning in 1977. Kipp also contends that the defendants failed to include specific questions relating to symptoms associated with AIDS (i.e., persistent cough or shortness of breath, white spots or unusual blemishes in the mouth, persistent diarrhea) on the health questionnaire card given to potential donors. Finally, Kipp argues that the defendants failed to provide a confidential means whereby donors can prevent their blood from being used for transfusions.

In fact, the record indicates that the defendants complied with the March 1983 FDA recommendations. And, at a minimum, they substantially complied with the December 1984 FDA recommendations which had not yet been adopted by the Army at the time of Cheryl Kipp's transfusion. For example, the specific AIDS-related symptoms that Kipp asserts needed to be on the donor card were contained in the informational pamphlet provided to Bonner. The one clear deviation was the date restriction on Haitian entrants, but as with the other alleged deficiencies, Kipp failed to demonstrate that Bonner's blood would not have been taken had the FDA recommendations been followed verbatim. Therefore, even if Kipp's factual assertions were entirely accurate, he has failed to demonstrate that his mother would not have contracted HIV had the defendants strictly complied with the FDA recommendations.

Kipp has attempted to remedy the lack of proof on proximate cause with two equally unpersuasive arguments. First, Kipp asserts that the blood transfusion with Bonner's contaminated blood is the only possible source of the AIDS virus contracted by his mother. While that may be true, the proper focus of our inquiry is whether the defendants' alleged negligence -- i.e., inadequate screening of potential donors -- caused Kipp's mother to contract the AIDS virus. Kipp's view of the requisite causation element erroneously focuses on the transfusion rather than on the alleged negligence. Second, at oral argument, Kipp's counsel erroneously attempted to place the essential, and independent, requirement of proximate cause under the umbrella of the negligence per se doctrine. As we noted previously, however, the negligence per se principle only establishes the duty and breach of duty elements of a negligence claim.3 Here, Kipp failed to demonstrate causation, i.e., that it was the Blood Center's inadequate screening of blood donors that caused Cheryl Kipp's death. arguments as to negligence per se are of no avail in proving the essential element of causation.

Because Kipp failed to prove causation, we need not discuss the other issues pertaining to his negligence claims. Moreover, we

³We recognize that some of the cases from Kentucky seem to suggest that the proximate cause requirement is satisfied when a statute is violated and the resulting injury is the type contemplated under the statute. See Blue Grass Restaurant Co., <u>Inc. v. Franklin</u>, 424 S.W.2d 594, 597 (Ky. 1968) ("The ordinance which was violated was intended to prevent the injury which [plaintiff] sustained, therefore, the failure to comply must be considered a proximate cause."). Later cases, however, make it clear that Kentucky law does require a plaintiff to prove causation, even in a negligence per se case. See, e.g., Tennyson, 823 F. Supp. at 422-24 (applying Kentucky law and rejecting the plaintiffs' argument that once the jury found the defendant's act to be negligence per se, "the court should have ruled as a matter of law that such negligence was a substantial factor in causing the collision"); <u>Britton v. Wooten</u>, 817 S.W.2d 443, 447 (Ky. 1991) (stating that violations of administrative regulations constitute negligence per se and the basis for liability "if found to be a substantial factor in causing the result"); Peak, 765 S.W.2d at 578.

have considered Kipp's argument that the district court erred in preventing his lay witnesses from testifying and find it to be without merit.

III. CONCLUSION

Kipp has failed to prove an essential element of his negligence claims, namely that the screening procedures used by the defendants caused his mother to contract AIDS. Therefore, we affirm the district court's order entering judgment for the defendants.

A true copy.

Attest:

CLERK, U. S. COURT OF APPEALS, EIGHTH CIRCUIT.